

Secretary's Advisory Committee on Xenotransplantation
February 20-21, 2001
DoubleTree Hotel, Rockville, Maryland

DRAFT Agenda

Day 1

- 8:30 a.m. **Welcome and Opening Remarks**
William Raub
Office of the Secretary, U.S. Department of Health and Human Services
- 8:40 a.m. **Swearing In of Committee Members**
David Satcher
Surgeon General of the United States
- 8:45 a.m. **Opening Remarks**
David Satcher
Surgeon General of the United States
- 9:00 a.m. **Introduction of the Committee**
Committee Members and Ex Officio Members
- 9:50 a.m. **Remarks by the Chair**
Harold Vanderpool
Chair, Secretary's Advisory Committee on Xenotransplantation
- 10:00 a.m. **Overview of the Federal Advisory Committee Act**
LaVerne Stringfield
Office of Federal Advisory Committee Policy, National Institutes of Health
- 10:10 a.m. **Ethics Rules for Federal Advisory Committee Members: Conflict of Interest, Outside Activities and Affiliations, and Confidentiality**
Karen Dalheim
Office of the General Counsel, U.S. Department of Health and Human Services
- Fran Plyler*
National Institutes of Health Ethics Coordinator
- 10:40 a.m. **Break**
- 10:55 a.m. **The Experimental and Clinical History of Xenotransplantation**
David K. C. Cooper
Harvard Medical School

11:10 a.m.	The Science of Xenotransplantation: Immunological Aspects <i>Hugh Auchincloss</i> <i>Harvard Medical School</i> Pre-clinical Animal Models <i>David White</i> <i>University of Western Ontario</i> Infectious Disease Risk <i>Jon Coffin</i> <i>Tufts University</i>
12:30 p.m.	Lunch Break
1:45 p.m.	Public Comment
2:15 p.m.	PHS Guidelines on Infectious Disease Issues In Xenotransplantation <i>Louisa Chapman</i> <i>Centers for Disease Control and Prevention</i>
2:50 p.m.	FDA Regulation of Xenotransplantation and Current Policy <i>Eda Bloom</i> <i>Food and Drug Administration</i>
3:30 p.m.	Break
3:45 p.m.	Overview of Xenotransplantation Clinical Trials <i>Louis Marzella</i> <i>Food and Drug Administration</i>
4:05 p.m.	Presentations on Xenotransplantation Clinical Trials: (Part I) The Excorp Medical Bioartificial Liver System <i>Daniel Miller</i> <i>Excorp Medical, Inc.</i>
4:25 p.m.	Schedule for Future SACX Meetings <i>Mary Groesch, Executive Director, SACX</i>
4:40 p.m.	Adjourn for the Day

Day 2

8:30 a.m.

Opening Remarks

Harold Vanderpool

8:40 a.m.

Presentations on Xenotransplantation Clinical Trials (Part II)

Jon Richards

Oncology Specialists, S.C.

E. Michael Egan

Diacrin, Inc.

9:40 a.m.

Public Comment

10:10 a.m.

Break

10:25 a.m.

Identification by SACX of Xenotransplantation Issues That Need To Be Addressed (*Discussion Moderator: Harold Vanderpool*)

- Science/medical (*Initial Remarks: Dan Salomon*)
- Safety/public health (*Initial Remarks: Marian Michaels, William Scheckler*)
- Ethical Issues (*Initial Remarks: Harold Vanderpool*)
- Animal welfare (*Initial Remarks: Lilly-Marlene Russow*)

12:00 p.m.

Lunch

1:15 p.m.

Identification of Issues, continued

- Socio-economic issues (*Initial Remarks: Alan Berger*)
- Legal issues (*Initial Remarks: Robyn Shapiro*)
- Psychological issues (*Initial Remarks: Catherine Crone*)
- Patient Responses (*Initial Remarks: James Finn, Karren King*)
- Federal Agency Perspectives (*SACX Ex Officio Members*)

4:15 p.m.

Closing Remarks

Harold Vanderpool

4:20 p.m.

Adjourn Meeting